REMARKS

Claims 1-25 of the subject application are pending. Applicants have amended claims 1-4, 10-13, 23, and 25. Applicants have not canceled any claims. Applicants have added new claims 26-27. Accordingly, claims 1-27 are present for further examination.

In view of the following discussion, applicants respectfully request that the Examiner reconsider and withdraw the rejections made in the outstanding Office Action.

Support for the Amendments

Applicants have amended claims 1-4, 7-13, 16, 18, 21, 23, and 25 in order to more clearly describe and distinctly claim the subject matter of applicants' process for preparing a monoketal compound and process for preparing 1, 4-cyclohexanedione mono-2, 2-dimethyl trimethylene ketal. Applicants have amended claims 1-4, 7-13, 16, 18, 21, 23, and 25 to correct certain minor procedural language. Applicants have added new claims 26-27 to recite a process for preparing a carbozole compound. These new claims are fully supported in applicants' specification.

Applicants have also amended the specification to correct an inadvertent typographical error. Applicants have deleted the reference to "U.S. Pat. No. 5,618,847" that does not relate to the invention, and have substituted therefor "U.S. Pat. No. 5,618,947", which patent describes a preparation of frovatriptan as mentioned in applicants' specification, as published, at paragraph 0028.

These amendments are fully supported in the specification as originally filed and, since no new matter is introduced by these amendments, the application is in compliance with 35 U.S.C. §132. Accordingly, applicants request entry of these amendments.

Foreign Priority Document

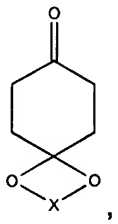
This application claims the benefit of the foreign application, INDIA 681/MAS/2002 with a filing date 13 September 2002 but a certified copy of the priority document had not previously been provided. Applicants were therefore requested to file the foreign priority document.

Applicants are obtaining a certified copy of the priority application, and expect to submit it soon.

Rejection of Claims 1-25 under 35 U.S.C. §103(a) as being unpatentable over *Courtet et al.*

The Examiner has rejected claims 1-25 under 35 U.S.C. §103(a) as being unpatentable over Bull. Soc. Chim. Fr., pp. 1493-1494 (1962) ("*Courtot*"). The Examiner states that *Courtot* discloses performing the instant preparation of the monoketal of cyclohexane 1, 4-dione using a diol of the instant formula, i.e., ethyleneglycol with the only difference being that benzene is used instead of a halogenated organic solvent. (p. 1494, col. 1, third paragraph). The Examiner argues that solvents such as the instantly used methylene chloride are commonly used in the formation of ketals as shown by WO03/010156 ("*Roques et al.*"), p. 1-5, and p. 5, lines 20-26). The Examiner concludes that one of ordinary skill would have found the instant process to be obvious. Applicants traverse the Examiner's rejection.

Applicants' claims provide a process for preparing a monoketal compound of the structure



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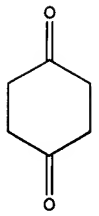
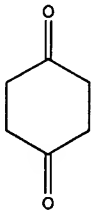
said process comprising reacting 1,4-cyclohexanedione of the structure



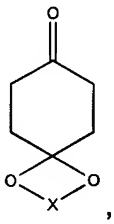
with a diol of the structure HO-X-OH in a halogenated organic solvent in the presence of an acid catalyst, wherein X is a substituted or unsubstituted ethylene or propylene.

Applicants' claims further provide a process for preparing 1, 4-cyclohexanedione mono-2, 2-dimethyl trimethylene ketal, said process comprising a) reacting 1, 4-cyclohexanedione and neopentyl glycol in dichloromethane or chloroform in the presence of sulfuric acid at about 25°C.-50°C.; b) removing dichloromethane or chloroform to provide a crude residue; c) combining an aliphatic or alicyclic hydrocarbon solvent with said crude residue to form a mixture; d) cooling said mixture to a temperature of about 0°C.-5°C.; and e) filtering the cooled mixture to remove undissolved impurities.

Applicants' claims still further provide a process for preparing a carbozole compound, which comprises the steps of:(a) reacting 1,4-cyclohexanedione of the structure



with a diol of the structure; HO-X-OH; in a halogenated organic solvent in the presence of an acid catalyst, wherein X is a substituted or unsubstituted ethylene or propylene, to form a monoketal compound of the structure:



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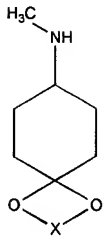
b) converting the monoketal compound from step a) by reductive amination to an alkylamino ketal of the structure;



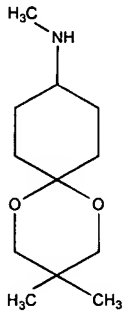
and c) reacting the alkylamino ketal from step b) with 4-carboxamidophenylhydrazine to form the carbozole compound.

The Examiner states that the *Courtot* reference discloses (in French) the preparation of 1, 4-dicyclohexanedione mono-dimethylene ketal by reacting 1, 4-dicyclohexanedione with ethlyene gylcol in benzene. The Examiner concedes that *Courtot* does not disclose the preparation of 1, 4-dicyclohexanedione mono-dimethylene ketal using a halogenated organic solvent in the presence of an acidic catalyst.

The *Roques et al.* reference discloses a method for preparing *α*-halogenoalkylaryl ketone cyclic ketals and *α*-halogenoalkylarylketones by reacting an alkylarylketone with a sulfuryl halide in the presence of an aliphatic diol capable of forming a cyclic ketal with the carbonyl function (English Abstract). This reference is also in French (with no identified English equivalent) and applicants do not see where solvents such as methylene chloride are used in the formation of ketals in the presence of an acidic catalyst.

Applicants submit that *Courtot* is silent regarding the preparation of 1, 4-dicyclohexanedione mono-dimethylene ketal using a halogenated organic solvent in the presence of an acidic catalyst. Furthermore, *Roques et al.* is silent regarding the preparation cyclic ketals using methylene chloride in the presence of an acidic catalyst. Both references are silent regarding the use of an acid catalyst. The combination of *Courtot* in view of *Roques et al.* does not teach or suggest applicants' process for preparing monoketal compounds in a halogenated organic solvent in the presence of an acid catalyst.

Moreover, the Examiner does not address applicants' claim 4, which recites a monoketal compound wherein the diol is neopentyl glycol, which monoketal compound is converted by reductive amination to an alkylamino ketal of the structure;



and b) reacting the above alkylamino ketal with 4-carboxamidophenylhydrazine to form frovatriptan.

The Examiner also does not address applicants' claim 25, which recites a process for preparing 1, 4-cyclohexanedione mono-2, 2-dimethyl trimethylene ketal. The process comprises a) reacting 1, 4-cyclohexanedione and neopentyl glycol in dichloromethane or chloroform in the presence of sulfuric acid at about 25°C.-50°C.; b) removing dichloromethane or chloroform to provide a crude residue; c) combining an aliphatic or alicyclic hydrocarbon solvent with said crude residue to form a mixture; d) cooling said mixture to a temperature of about 0°C.-5°C.; and e) filtering the cooled mixture to remove undissolved impurities.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 706.02(j).

The initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the

claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp,* 227 USPQ 972. 973 (Bd. Pat. App. & Inter. 1985). MPEP 706.02(j)

Accordingly, the Examiner's rejection of claims 1-25 under 35 U.S.C. §103(a) as being unpatentable over *Courtot* in view of *Roques et al.* should be withdrawn.

Obviousness of a composition or process must be predicated on something more than it would be obvious "to try" the particular component recited in the claims or the possibility it will be considered in the future, having been neglected in the past. *Ex parte Argabright et al.* (POBA 1967) 161 U.S.P.Q. 703. There is usually an element of "obvious to try" in any research endeavor, since such research is not undertaken with complete blindness but with some semblance of a chance of success. "Obvious to try" is not a valid test of patentability. *In re Mercier* (CCPA 1975) 515 F2d 1161, 185 U.S.P.Q. 774; *Hybritech Inc. v. Monoclonal Antibodies. Inc.* (Fed. Cir. 1986) 802 F.2d 1367, 231 U.S.P.Q. 81; *Ex parte Old* (BPAI 1985) 229 U.S.P.Q. 196; *In re Geiger* (CAFC 1987) 815 F.2d 686, 2 U.S.P.Q.2d 1276. *In re Dow Chemical Co.* (Fed. Cir. 1988), 837 F.2d 469, 5 U.S.P.Q.2d 1529. Patentability determinations based on that as a test are contrary to statute. *In re Antonie* (CCPA 1977) 559 F.2d 618, 195 U.S.P.Q. 6; *In re Goodwin et al.* (CCPA 1978) 576 F.2d 375, 198 U.S.P.Q. 1; *In re Tomlinson et al.* (CCPA 1966) 363 F.2d 928, 150 U.S.P.Q. 623. A rejection based on the opinion of the Examiner that it would be "obvious to try the chemical used in the claimed process which imparted novelty to the process does not meet the requirement of the statute (35 U.S.C. 103) that the issue of obviousness be based on the subject matter as a whole. *In re Dien* (CCPA 1967) 371 F.2d 886, 152 U.S.P.Q. 550; *In re Wiaains* (CCPA 1968) 397 F.2d 356, 158 U.S.P.Q. 199; *In re Yates* (CCPA 1981) 663 F.2d 1054, 211 U.S.P.Q. 1149. Arguing that mere routine experimentation was involved overlooks the second sentence of 35 USC 103. *In re Saether* (CCPA 1974) 492 F.2d 849,181 U.S.P.Q. 36. The issue is whether the experimentation is within the teachings of the prior art. *In re Waymouth et al.* (CCPA 1974) 499 F.2d 1273, 182 U.S.P.Q. 290. The

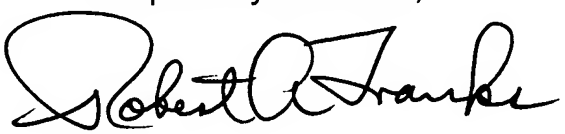
fact that the prior art does not lead one skilled in the art to expect the process used to produce the claimed product would fail does not establish obviousness. *In re Dow Chem. Co.* (Fed. Cir. 1988) 837 F.2d 469, 5 U.S.P.Q.2d 1529.

The provisions of Section 103 must be followed realistically to develop the factual background against which the Section 103 determination must be made. It is not proper within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggest to one of ordinary skill in the art. The references of record fail to teach or suggest applicant's invention as a whole.

CONCLUSION

In view of the foregoing Amendment and Response, applicants request reconsideration pursuant to 37 C.F.R. §112 and allowance of the claims pending in this application. Applicant requests the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments, which might be most expeditiously handled by a telephone conference or personal interview. If any additional fee is required in connection with this submission, authorization is hereby given to charge the amount of such fee to Deposit Account No. 50-3221.

Respectfully submitted,



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